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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,122

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Nobushige Itaya

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22428 7590 07/09/2009  
FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,122	<b>Applicant(s)</b> ITAYA ET AL.	
	<b>Examiner</b> SUSANNAH CHUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 13-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 9-10, 13-19 are pending in the instant application. Claims 1-8, and 11-12 are canceled. Claims 13-19 are new.

#### ***Response to Non-Final Office Action***

Acknowledgment is made of applicant's response and amendment of the claims filed on 4/21/2009.

Claims 1-10 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claims omit essential steps. Applicants arguments and amendment to the claims are acknowledged. This rejection is withdrawn as to the remaining claims, i.e. claims 9 and 10, in view of the amendment to the claims and arguments.

Claims 11 and 12 were rejected under 35 U.S.C. 103(a) as being obvious over Daumas et al (US Patent No. 5,371,233 ('233 Pat)). This rejection is withdrawn in view of the deletion of claims 11 and 12.

Claims 1-10 were rejected under 35 U.S.C. 103(a) as being obvious over Daumas et al (US Patent No. 5,371,233 ('233 Pat) in view of Buhlmayer et al. (US Pat No. 5,399,578 ('578 Pat) or US Pat No. 5,965,592 ('592 Pat)). Applicants arguments and amendment to the claims are acknowledged, but are not found persuasive. The following refers to the remaining claims, i.e. claims 9, 10, 13-18 and 19. First, Applicants argue that Daumas uses anhydrous tetrahydrofuran, while the instant claims do not use anhydrous tetrahydrofuran. The term anhydrous generally refers to the

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absence of water. It is known in the art that anhydrous solvents can be purchased and may be advantageous due to the lack of water, but it is known in the art that regular and anhydrous solvents are interchangeable. Also, the prior art refers to anhydrous tetrahydrofuran as well as tetrahydrofuran (not anhydrous). See US Pat No 5,371,233, column 5, approximately lines 34-36, Example 1, Method 1, wherein anhydrous tetrahydrofuran and tetrahydrofuran are used. Absent unexpected results, it would be known to one of ordinary skill that the amount of water in the tetrahydrofuran will not have any unexpected qualities. Second, Applicants argue that there is no motivation to combine the Daumas and Buhlmayer references. It is well known in the art that the Buhlmayer reference is the original valsartan patent and an artisan working with valsartan will also be aware of the contents of Buhlmayer. The Daumas reference is directed to the purification of valsartan like in the instant claims. Therefore, the combination of both Daumas and Buhlmayer would be known to a skilled artisan working with valsartan. Third, Applicants state that the instant process yields unexpected results that are superior to the prior art. This is acknowledged, but not found persuasive. Claims will be given their broadest reasonable interpretation. The instant claims do not discuss purity of the compounds other than to say that they are "a highly pure crystal." This term can be interpreted in many different ways. A highly pure crystal can have a significant amount of impurity and still be deemed pure by one of ordinary skill in the art. Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted. Ex parte Fressola, 27 USPQ 2d 1608. It is also asserted that the selection of reaction

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conditions is more optimization by more modification of routine experimentation and within one skilled in the art. Changes in temperature, concentration, or both is not patentable modification in the absence of unexpected results which is different in kind and not degree. In re Aller, 105 USPQ 233. Therefore, in view of the broad claim language and lack of a declaration showing unexpected results, it appears that the instant claims do not show unexpected results.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted. Ex parte Fressola, 27 USPQ 2d 1608. Claims that require one to read the specification to determine the metes and bounds of the invention are repugnant to modern practice in the Office and are properly rejected under 35 USC 112, 2<sup>nd</sup> paragraph, as failing to particularly point out and distinctly claim the invention. Id. At 1609.

Claims 13-19 are drawn to a process, but use broad terms such as “an azide of organic base,” “solvent,” “radical initiator,” and “oxidizer” are unclear and it is not possible to ascertain the metes and bounds of the claim without reading the specification into the claim. Claims that do not stand alone to define the invention are

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not permitted. Id. at 1608. Applicant can overcome this rejection by defining the “azide of organic base” as sodium azide and “solvent” as tetrahydrofuran.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/  
Primary Examiner, Art Unit 1626

Susannah Chung